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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,305	08/20/2001	Markus Albers	LEA33324	9002

7590 08/04/2003  
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EXAMINER

MCKENZIE, THOMAS C

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 08/04/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/868,305

Applicant(s)

ALBERS ET AL.

Examiner

Thomas McKenzie, Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 24-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

1. This action is in response to amendments filed on 5/21/03. Applicant has cancelled all pending claims. Claims 24-43 are new. Claims 24-27 are compound claims. Claim 43 is a composition claim. Claims 35-42 are use claims. Claims 28-34 are synthesis claims. This is the second action on the merits. The application concerns some biphenyl compounds, compositions, and uses thereof.

***Response to Amendment***

2. Applicants' new claims overcome the objection made in point #4 of the previous office action. Applicants' claims no longer contain the limitation "fluoro residues". Thus, the objection made in point #5 is moot. Applicants' deletion of "general" overcomes the indefiniteness rejection made in point #6. Applicants specified list of substituents overcomes the indefiniteness rejection made in point #7. Applicants' claims no longer contain reference to substituted benzoyl or tolyl radicals. Thus, the rejection made in point #10 is moot. Applicants' claims no longer contain reference to "a integrin-mediated disease". Thus, the indefiniteness rejection made in point #11 is moot. Applicants' claims no longer contain reference to preventing diseases. Thus, the enablement rejection made in point #12 is withdrawn. Applicants' deletion of claims to cancer treatment generally and "ophthalmic" diseases, overcome the enablement rejection made in points #14 and #15. Applicants' specific list of R<sup>2</sup> radicals does not include the heterocyclic

pyrrolidine substituted by 3,5-dichlorophenyl)sulfonyl taught by Durette ('511). Thus, the art rejection made in point #16 is overcome. Applicants' requirement that both  $R^2$  radicals in  $NR^2COR^2$  be the same overcomes the art rejection over Burk (Journal of the American Chemical Society) made in point #17. Burk (Journal of the American Chemical Society) requires  $R^2 =$  hydrogen and methyl simultaneously and does teach or suggest the formamide compound with both  $R^2 =$  hydrogen.

***Claim Rejections - 35 USC § 112***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 24-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The definitions of  $R^3$ - $R^6$  in claims 24 and 26 indicate that two of these radicals may form a ring "which contain further heteroatoms". What heteroatoms are permitted? Are they oxygen, nitrogen, and sulfur or is a metal or a halogen permitted? What is the size of this ring? Is there any limit? What other atoms are intended? How many additional non-carbon atoms may be present? For example in the passage spanning line 5, page 61 to line 2, page 62, Applicants describe the ring formed by  $R^3$  and  $R^4$ . Applicants use open language "can be selected from the

following nonexclusive list:". The following structures are five to seven-membered and contain a single nitrogen, sulfur, or oxygen atom. Is this all?

Applicants make no argument concerning this rejection.

4. Claims 26-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "alkynyl residue" occurs in claim 26 in the definition of radical  $R^2$ . It occurs also in line 25, page 48 of the specification but is not further defined. Is the alkynyl radical, containing a carbon-to-carbon triple bond, intended?

Applicants make no argument concerning this rejection.

5. Claims 35 and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating the other listed diseases of claim 35, does not reasonably provide enablement for inhibiting angiogenesis generally. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. According to the On-line Medical Dictionary at <http://cancerweb.ncl.ac.uk/omd/index.html>, angiogenesis is "The process of vascularisation of a tissue involving the development of new capillary blood vessels". As such it is a normal process occurring in healthy tissue,

particular during development. This claim would read on inhibiting angiogenesis in mammals with below normal angiogenesis activity, inhibiting angiogenesis in mammals with normal angiogenesis activity, or in asymptomatic mammals with up-regulated angiogenesis activity. The specification fails to teach any benefit to be gained from such actions. In fact, those actions would sound dangerous. How is the skilled physician to use the invention in the situations described above?

Applicants make no argument concerning this rejection.

#### ***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January

1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24, 25, and 35-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,420,396 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound of claim 1 of U.S. Patent No. 6,420,396 B1 is a species embraced by the generic formula of the present claim 24. The compound of claim 1 of U.S. Patent No. 6,420,396 B1 fits formula (1) with  $R^1 = R^1$ ,  $R^2 = NR^2'SO_2R^2''$ ,  $R^{2'} = \text{hydrogen}$ ,  $R^{2''} = C_6H_2(CH_3)_3$ ,  $U =$   $W =$  a direct bond,  $V =$  the alkylene group  $CH_2$ ,  $A = 1,4\text{-phenylene}$ ,  $B = 1,3\text{-phenylene}$ ,  $R^3 = \text{group (a14)}$ , and  $R^4 = \text{hydrogen}$ . According to the MPEP §806.04(i) "Generic Claims Presented for First Time After Issue of Species. The Office no longer follows the practice of prohibiting the allowance of generic claims that are presented for the first time after the issuance of a copending application claiming plural species. Instead, the Office may reject the generic claims on the grounds of obviousness-type double patenting. Applicant may overcome such a rejection by filing a terminal disclaimer. See *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29."

7. Claims 24-43 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 12-18, 23, and 34-41 of copending Application No. 09/828,514. Although the conflicting claims are not identical, they are not patentably distinct from each other because except for the addition of  $R^{2''}$  = hydrogen and the addition of a proviso to claim 1 of copending Application No. 09/828,514, the Examiner can see no difference between the two claims 1. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants state that terminal disclaimers for both U.S. Patent No. 6,420,396 B1 and Application No. 09/828,514 have been filed. These have not matched with the present case. Applicants have filed a terminal disclaimer in copending Application No. 09/828,514 but not in this case.

***Allowable Subject Matter***

8. Applicants compounds are novel over Briza (Eur. J. Biochem.) who teaches a compound with formula (1) with  $R^1$  = hydrogen,  $R^2$  =  $NR^{2'}COR^{2'}$ ,  $R^{2'}$  = hydrogen, U = a direct bond, V = the alkylene group  $CH_2$ , A = B = 1,3-phenylene,  $R^3$  =  $R^4$  = hydrogen, and W = the ethylene group substituted by carboxyl. Both phenylene rings have a hydroxyl group in the 6-position, not permitted by Applicants' claim limitations.



**Conclusion**

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for after final amendments is (703) 872-9307. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mukund Shah can be reached on (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.

*Mukund Shah*

**Mukund Shah**  
**Supervisory Patent Examiner**  
**Art Unit 1624**

TCMcK  
July 31, 2003

